

preference of physicians in prescribing Oral Antidiabetic Treatments (OATs) versus Insulin in Diabetes patients. **METHODS:** A survey was conducted by CSD, face to face interviews with 200 physicians of several specialties, GPs, diabetologists, endocrinologists who treat at least 30 diabetic patients/month. The sample emerged from four capital cities of Greece. The sampling method was based on stratified random sample. Interviews were conducted from May 12 to June 3, 2009. Results were weighted according to the actual distribution of specialties. **RESULTS:** The number of patients with type-1 diabetes is approximately 12% and 88% with type-1 diabetes. In DT1 100% patients receive insulin, contrary to DT2 where patients receive 23% insulin and 83% OATs. Overall, 60% of T2D patients are regulated. Also when adding a third OAT drug 54% of the patients will delay the use of insulin. Unmet needs mentioned spontaneously by physicians are: a) poor compliance to treatment; b) poor compliance to diet; and c) high cost of co-payment for medicines. **CONCLUSIONS:** Based on the results of the present study, physicians use insulins for DT1 patients and they prefer OATs for T1ID. The economic burden of T1ID patients is heavy due to high co-payment rate, which might be linked to poorly regulated patients leading to higher incidence of diabetes-related complications.

PDB71

#### GLYCAEMIC AND CHOLESTEROL CONTROL OF TYPE 2 DIABETIC PATIENTS ATTENDING SPECIALIST OUTPATIENT CLINICS IN SINGAPORE

Lim BK<sup>1</sup>, Toh MPH<sup>1</sup>, Cheah TS<sup>2</sup>, Sum Chee F<sup>2</sup>, Jong M<sup>3</sup>, Chionh SB<sup>4</sup>

<sup>1</sup>National Healthcare Group, Singapore, Singapore, <sup>2</sup>Alexandra Hospital, Singapore, Singapore, <sup>3</sup>Tan Tock Seng Hospital, Singapore, Singapore, <sup>4</sup>National University Hospital, Singapore, Singapore

**OBJECTIVES:** The specialist outpatient clinics (SOCs) of the 3 acute hospitals of the National Healthcare Group (NHG) in Singapore treat over 11,000 patients with diabetes mellitus. This paper studies the glycaemic and cholesterol control of type 2 diabetes mellitus (T2DM) patients at these SOCs. **METHODS:** This study included all patients with T2DM who attended the hospital SOCs in Jan 2009 for treatment of diabetes. These patients had been on follow-up at the same clinic for at least 12 months. The latest glycated haemoglobin (HbA1c) and LDL-cholesterol (LDL-c) results were compared by age, gender and ethnic group. Data was extracted from the NHG Diabetes Registry (CDMS). **RESULTS:** There were 3,420 T2DM patients with more females (53%) and disproportionately more Indians (14.1%) and fewer Chinese (66.3%) than the general population. The mean ages of male and female were 61.8 and 64.9 years respectively. The proportion of patients with "optimal" HbA1c ( $\leq 7\%$ ) and LDL-c ( $< 2.6$  mmol/L) control increased with age. For HbA1c, 13% of patients  $< 35$  years had "optimal" control (mean 8.96%, 95%CI 8.42–9.50%) increasing to 61% for patients 85+ years (mean 7.04%, 95%CI 6.79–7.28%). Similarly for LDL-c, 41% of patients  $< 35$  years had "optimal" control (mean 2.92 mmol/L, 95%CI 2.63–3.21 mmol/L), increasing to 74% for patients 85+ years (mean 2.28 mmol/L, 95%CI 2.14–2.41 mmol/L). Chinese had better HbA1c and LDL-c control whilst Malay and Indian were poorest for LDL-c and HbA1c respectively. There was no gender difference. **CONCLUSIONS:** The control of HbA1c and LDL-c among T2DM patients improved with age. Younger patients and the Malay and Indian subgroups had greater potential to achieve "optimal" glycaemic and cholesterol control and reduce the risk of developing micro- and macro-vascular complications over time. While the older patients achieved better HbA1c control than younger ones, clinicians should remain mindful of side-effects such as hypoglycaemia among those with very tight glycaemic control.

PDB72

#### QUALITY ADJUSTED LIFE YEARS LOSS DUE TO TYPE 2 DIABETES IN SOUTH KOREA

Jo MW<sup>1</sup>, Lee WJ<sup>1</sup>, Noh JH<sup>2</sup>, Choi Y<sup>3</sup>, Song KH<sup>4</sup>

<sup>1</sup>University of Ulsan, Seoul, South Korea, <sup>2</sup>Inje University Ilsan Paik Hospital, Ilsan, Gyeonggi-Do, South Korea, <sup>3</sup>Sanofi-aventis Korea, Seoul, South Korea, <sup>4</sup>Kunkuk University Hospital, Seoul, South Korea

**OBJECTIVES:** This study was conducted to estimate quality adjusted life years (QALYs) loss due to diabetes in type 2 diabetic patients of South Korea. **METHODS:** In order to obtain QALYs loss due to morbidity of type 2 diabetes (T2D), we firstly estimated utility weight difference between T2D patients and non-diabetic subjects by sex and age groups. We consecutively recruited T2D patients aged 20 or over who visited three university hospitals in Seoul and Ilsan from October 2007 to January 2008 and non-diabetic subjects who took a medical examination from June 2008 to Jan 2009 in same hospitals. Utility weight differences on sex and age groups were calculated using the EuroQoL EQ-5D and Korean valuation set, and then QALY losses was estimated using the utilities and the number of T2D patients in 2003 reported by the Korean Diabetes Basic Statistics Study. QALY losses due to T2D mortality corresponded to life expectancy of the death caused T2D from the life table and the Korean Death Certificate in 2003 multiplied by utility weights of healthy people by sex and age groups from the 3<sup>rd</sup> Korea National Health and Nutrition Examination Survey (2005). We considered a discount rate as 5%. **RESULTS:** Total 1,072 T2D patients and 387 non-diabetic subjects participated in this survey. Maximum difference between T2D patients and non-diabetic subjects was 0.0418 and minimum difference was 0.0095 by subgroups. QALY loss estimates due to T2D morbidity were about 35,125 QALYs in male and 50,613 QALYs in female. Preterm death caused by T2D brought about 58,186 QALYs in male and 49,432 QALYs in female considering the discount rate. Therefore, total QALY loss was estimated as 193,356 QALYs annually. **CONCLUSIONS:** The results suggest that QALY loss estimates caused by T2D was 4.0 QALYs/1000 persons in South Korea at 2003.

PDB73

#### ANALYSIS OF FACTORS INFLUENCING DECISION MAKING ON TYPE 2 DIABETES DRUGS IN 5 HTA-AGENCIES

Adalsteinsson E<sup>1</sup>, Jensen RC<sup>2</sup>, Mondher T<sup>3</sup>, Hemels M<sup>4</sup>

<sup>1</sup>Novo Nordisk, Søborg, Denmark, <sup>2</sup>Novo Nordisk A/S, Bagsværd, Denmark, <sup>3</sup>University Claude Bernard Lyon, Lyon, France, <sup>4</sup>Novo Nordisk A/S, bagsværd, Denmark

**OBJECTIVES:** To map factors that influence HTA-agencies in their Health Technology Assessments (HTA) on type 2-diabetes agents in the UK (NICE), Scotland (SMC), The Netherlands (CVZ) Germany (IQWiG) and Sweden (TLV). **METHODS:** To retrieve the HTA reports, a search was executed using the agencies websites with the following keywords: pioglitazone, rosiglitazone, sitagliptin, vildagliptin, exenatide, glargine, detemir, aspart, glulisine and lispro. If a report contained several drugs each drug was counted separately although a decision could involve a class of drugs. Decision parameters were clustered in three categories: efficacy, safety and health economics where each assessment could contain multiple parameters. Overall recommendation was classified in three categories: recommended restricted recommended and not recommended in relation to indication based on marketing authorisation. **RESULTS:** 35 reports were identified with 49 assessments. Twelve assessments lead to recommendation (24%), 23 to restricted recommendation (47%) and fourteen to no recommendation (29%). Reasons for recommending a treatment contained in 83% of cases one or more arguments related to efficacy, 33% to safety, and 66% to health economic aspects of drugs. Reasons for restricted recommendation were 70%, 39%, and 60%, and for not recommended were 100%, 57% and 21% respectively. Within each decision parameter the most common reason for restricting the market authorization indication was related to the drug not being cost-effective (57%). The most common reason for not recommending a drug was lack of long term data on efficacy (86%). **CONCLUSIONS:** Despite that large variations in results between agencies were observed, data demonstrating efficacy of the drug appeared to be the most important factor in getting a recommendation for type 2 diabetes treatment. A high incremental cost-effectiveness ratio was likely to lead to restrictions in indication (NICE, SMC and TLV) whereas lack of long term data could lead to the drug not being recommended (IQWiG and CVZ).

PDB74

#### ETHICAL DILEMMAS OF PHARMACOLOGICAL TREATMENT AND SELF MANAGEMENT OF DIABETES—A REVIEW OF THE LITERATURE

Jensen RC<sup>1</sup>, Kaas C<sup>2</sup>, Mondher T<sup>3</sup>, Hemels M<sup>4</sup>

<sup>1</sup>Novo Nordisk A/S, Bagsværd, Denmark, <sup>2</sup>Copenhagen University, Copenhagen, Denmark, <sup>3</sup>University Claude Bernard Lyon, Lyon, France, <sup>4</sup>Novo Nordisk A/S, bagsværd, Denmark

**OBJECTIVES:** There is increasing focus on the ethical analysis in Health Technology Assessments (HTA). Due to the escalating epidemic of diabetes, diabetes has become an urgent health concern. We therefore systematically reviewed published articles describing the ethical aspects of pharmacological treatment and self management of diabetes. **METHODS:** PubMed was searched from inception to 2009 using the following combinations of keywords: ethics AND diabetes NOT screening NOT transplant. Articles were initially screened for relevance by reading title and abstract. If deemed appropriate, by two independent reviewers, full copies of the remaining articles were retrieved for further review. **RESULTS:** Out of 336 articles, only six studies were deemed appropriate. The main reason for this high level of rejected articles was that the majority of identified articles commented on the ethical approval in connection to conducting clinical studies rather than on the ethical aspects of implementing and using the specific technology. One study described the ethical concern related to the costly late complications of diabetes compared to preventing late complications by prescribing and reimbursing insulin. Other ethical issues concerned self management and the transferral of responsibility from physician to patient and the patient's capabilities for self management. For people with impaired glucose tolerance there were also ethical issues related to initiating a preventive pharmacological treatment of the "otherwise well". Lastly, there is an ethical issue between the normative gold standard for a healthy and moral lifestyle and a culture of self that values authenticity and originality. **CONCLUSIONS:** Due to the escalating prevalence of diabetes and emphasis on ethical analysis in HTAs, both payers and the industry needs to get a better understanding of the ethical aspects of self management and pharmacological treatment of diabetes. More research should be allocated towards investigating the ethical aspects of self management and pharmacological treatment of diabetes.

PDB75

#### APPLICATION OF HTA TO ANTIDIABETIC DRUG FORMULARY DECISIONS

Andreykiv M, Wiebinga C

Quintiles Consulting, Hoofddorp, The Netherlands

**OBJECTIVES:** To compare Health Technology Assessments (HTAs) and reimbursement decisions of a novel antidiabetic drug class, by health care agencies worldwide. **METHODS:** We conducted manual searches of 54 health care agencies' web sites from January 2008 to May 2009. HTAs regarding diabetes were collected and each was assessed for date, type (e.g., single drug versus class review) and scope (e.g., medicine name). Using a standardized set of categorical criteria, we investigated recommendations, as well as presence of supporting evidence (e.g., reported outcome measures, information sources, and key decision drivers). **RESULTS:** A total of 21 completed diabetes assessments were assessed. Data were retrieved from 9 agencies in 9 countries. The agencies published 21 assessments on diabetes during the review period; including 4 clinical guidelines, 9 single drug appraisals and 8 class reviews. Of

the 6 agencies (9 publications) that evaluated DPP-4 inhibitors, 2 recommended the drug not be listed or funded (CADTH, AHTAPol) and 4 recommended restricted use (PBAC, SMC, CVZ and NICE). The most common reason for agency's disinclination for listing/funding was insufficient information on the effectiveness and cost-effectiveness in the specified patient population. There are more than 100 HTAs ongoing in the endocrine nutritional and metabolic therapeutic area, approximately half of them (49 projects) concern diabetes, 21 of which evaluate pharmacological treatment of diabetes (8 countries, 11 agencies). **CONCLUSIONS:** Diabetes prevalence is on the rise, attracting increasing attention from health care agencies. Despite using similar data sources variable outcomes suggest to us that agencies are applying different weightings in their assessment process. The apparent failure to demonstrate effectiveness in specified populations suggests late segmentation by manufacturers and insufficient resourcing to generate data. This is often due to late payer requests for such analyses motivated by financial considerations. Early segmentation and engagement with payers is thus critical for HTA success.

PDB76

#### ETHICAL ANALYSES IN HEALTH TECHNOLOGY ASSESSMENTS OF DIABETES TREATMENTS

Kaas C<sup>1</sup>, Jensen RC<sup>2</sup>, Adalsteinsson E<sup>3</sup>

<sup>1</sup>Copenhagen University, Copenhagen, Denmark, <sup>2</sup>Novo Nordisk A/S, Bagsvaerd, Denmark,

<sup>3</sup>Novo Nordisk A/S, Søborg, Denmark

**OBJECTIVES:** Health Technology Assessment (HTA) is mostly known for its health economic properties even though it is a multidisciplinary form of policy research examining short- and long-term consequences of the application of a health technology. There is an increased focus on ethical analyses in HTA. A descriptive analysis was conducted on diabetes HTA reports describing ethical analyses. **METHODS:** The NHS Centre for Reviews and Dissemination HTA database (<http://www.crd.york.ac.uk/crdweb/>) was searched (1991–2009) using the keyword 'diabet\*'. HTA reports in English language assessing diabetes treatments were included and screened for any type of ethical analyses. **RESULTS:** Of 263 HTA reports identified in the initial search, 60 met the inclusion criteria. 4 reports included a type of ethical analysis (2 from CADTH, Canada; 1 from AHTA, Australia and 1 from NZHTA, New Zealand). CADTH conducted ethical analyses on short- and long-acting insulin analogues respectively, concluding that both types of insulin analogues did not exacerbate—might even better—the psychosocial issues of diabetes, however more quality-of-life evidence were needed. In AHTA's assessment of a continuous glucose monitoring device they described equity and access issues related to costs, and that the device could not replace standard of care, but should be used as an adjunct. NZHTA's assessment of continuous glucose monitoring devices was also related to equity concerns, concluding a need for more affordable devices. **CONCLUSIONS:** Ethical analyses are sparse in diabetes, despite stated objectives of best practice and HTA definitions. In the identified cases, ethical analyses were targeted to meet patients' needs as well as a tool to restrict access for the purpose of fair distribution in government funded health care systems. Further research on the methods of ethical analyses is warranted as well as the formulation of guidelines to fully estimate the value and ensure an optimal role for ethical analyses in HTA.

PDB77

#### BASAL CHARACTERISTICS OF PATIENTS BEGINNING BASAL, BASAL PLUS SHORT-ACTING, SHORT-ACTING OR PREMIX INSULIN: DATA FROM THE CREDIT STUDY

Home P<sup>1</sup>, Blonde L<sup>2</sup>, Marre M<sup>3</sup>, Admane K<sup>4</sup>, Vespasiani G<sup>5</sup>

<sup>1</sup>Newcastle University, Newcastle upon Tyne, UK, <sup>2</sup>Ochsner Medical Center, New Orleans, LA, USA, <sup>3</sup>Université Paris, INSERM U695, Paris, France, <sup>4</sup>Sanofi-Aventis, Paris, France,

<sup>5</sup>Diabetology and Metabolic Disorders Centre, Ascoli Piceno, San Benedetto del Tronto, Italy

**OBJECTIVES:** The ongoing Cardiovascular (CV) Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is assessing the effect of insulin on the risk of vascular events. **METHODS:** CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia, and includes 3031 people with T2DM who recently started basal and/or short-acting insulin, premix insulin or another insulin type. This analysis examines and compares the characteristics between groups starting basal (n = 1563), basal + short-acting (n = 444), short-acting (n = 221), premixed (n = 700) or another (n = 103) insulin. **RESULTS:** Demographic and diabetes characteristics were reasonably balanced between the insulin groups, although those receiving basal plus short-acting insulin or premix had a trend to higher baseline HbA<sub>1c</sub> levels vs other insulin types (basal, 9.2 ± 1.8%; basal + short-acting, 10.1 ± 2.2%; short-acting, 9.4 ± 2.0%; premix, 9.9 ± 2.0%; other, 9.1 ± 2.0%). While the majority had previously used oral glucose lowering drugs (OGLDs) (basal, 97%; basal + short-acting, 83%; short-acting, 83%; premix, 94%; other, 85%), differences in the numbers continuing OGLDs when beginning insulin were found. Continued use of OGLDs was highest with basal insulin (89%) versus the other insulins (basal + short-acting, 36%; short-acting, 45%; premix, 62%; other, 34%). However, the distribution of types of OGLD used before insulin was similar between the groups. There are no clear patterns in CV risk profile by insulin type. Previous diagnosis of hypertension (basal, 71%; basal + short-acting, 65%; short-acting, 57%; premix, 69%; other, 72%), family history of CV disease (basal, 29%; basal + short-acting, 25%; short-acting, 21%; premix, 23%; other, 14%) and body mass index tended to be lower in the short-acting insulin group. However, triglyceride levels were lower in the short-acting and 'other' insulin groups vs premix, basal and basal plus short-acting groups. **CONCLUSIONS:** People starting different insulins have

somewhat different clinical characteristics, which may confound attempts to compare future vascular outcomes between regimens.

PDB78

#### DIFFERENCES IN THE CHARACTERISTICS OF PEOPLE WITH TYPE 2 DIABETES STARTING INSULIN IN THE NORTH, SOUTH AND EAST OF EUROPE: DATA FROM THE CREDIT STUDY

Marre M<sup>1</sup>, Home P<sup>2</sup>, Vespasiani G<sup>3</sup>, Admane K<sup>4</sup>, Blonde L<sup>5</sup>

<sup>1</sup>Université Paris, INSERM U695, Paris, France, <sup>2</sup>University of Newcastle upon Tyne,

Newcastle upon Tyne, UK, <sup>3</sup>Diabetology and Metabolic Disorders Centre, Ascoli Piceno, San

Benedetto del Tronto, Italy, <sup>4</sup>Sanofi-Aventis, Paris, France, <sup>5</sup>Ochsner Medical Center, New Orleans, LA, USA

**OBJECTIVES:** Maintaining long-term glycaemic control with insulin therapy can reduce the risk of vascular events associated with Type-2 diabetes mellitus (T2DM). The Cardiovascular (CV) Risk Evaluation in people with T2DM on Insulin Therapy (CREDIT) study is an ongoing 4-year, noninterventional trial in 314 centres across North America, Europe and Asia. **METHODS:** People with T2DM who recently started insulin were included. Here we report variation in baseline characteristics of participants in eastern vs northern vs southern Europe. **RESULTS:** Marked differences in participant characteristics were found between eastern Europe (n = 735), northern (n = 460) and southern Europe (n = 647), including proportion of males (25 vs. 61 vs. 56%), diabetes duration (8 ± 5 vs. 9 ± 6 vs. 13 ± 9 years), age (58 ± 8 vs. 63 ± 11 vs. 63 ± 11 years) and HbA<sub>1c</sub> (9.7 ± 1.9 vs. 9.1 ± 2.0 vs. 9.3 ± 1.9%). Combinations of oral glucose-lowering drugs were common before insulin; sulfonylureas were dominant in eastern Europe and metformin elsewhere. Over 80% were taking non-glucose medications before insulin initiation, most commonly ARBs. People in eastern Europe had a greater family history of CV disease, were less physically active, but were not more obese (BMI: 30.7 ± 5.4 vs. 31.5 ± 6.3 vs. 29.6 ± 5.9 kg/m<sup>2</sup>). Rates of hypertension were lowest in southern Europe. HDL cholesterol in males was lowest in northern Europe and in females was highest in eastern Europe. LDL cholesterol was highest in southern Europe. Total cholesterol levels were lowest, but triglyceride levels were highest in northern Europe. Smoking was less prevalent in eastern Europe. Most people began with a basal insulin regimen (60 vs 63 vs. 62%); more people used meal-time insulin in eastern Europe (19 vs. 11 vs. 17%) and pre-mixes in northern Europe (22 vs. 28 vs. 13%). **CONCLUSIONS:** Baseline characteristics of people starting insulin reveals some striking differences between European regions; how these translate into CV events as the study progresses will be of interest.

PDB79

#### DO PEOPLE BEGINNING BASAL INSULIN HAVE A DISTINCT CLINICAL PROFILE COMPARED WITH THE OVERALL POPULATION IN THE CREDIT STUDY?

Vespasiani G<sup>1</sup>, Marre M<sup>2</sup>, Blonde L<sup>3</sup>, Admane K<sup>4</sup>, Home P<sup>5</sup>

<sup>1</sup>Diabetology and Metabolic Disorders Centre, Ascoli Piceno, San Benedetto del Tronto,

Italy, <sup>2</sup>Université Paris, INSERM U695, Paris, France, <sup>3</sup>Ochsner Medical Center, New Orleans,

LA, USA, <sup>4</sup>Sanofi-Aventis, Paris, France, <sup>5</sup>University of Newcastle upon Tyne, Newcastle

upon Tyne, UK

**OBJECTIVES:** The Cardiovascular Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is evaluating the effect of insulin on the risk of vascular events, which can be reduced via long-term glycaemic control. **METHODS:** CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia. It includes 3031 people with T2DM who had recently started basal, short-acting or premix insulin, over half of whom received basal insulin alone (n = 1563). This analysis examines the baseline characteristics amongst the subgroup initiating basal insulin after oral failure and compares them with those of the wider CREDIT population. **RESULTS:** The mean starting dose of basal insulin was 14.7 IU/day, administered once daily in 86% of participants. Of these, 61% took their injection at bedtime, 21% at breakfast, 17% at dinner and 1% at lunch. Over 90% used pen devices, split equally between disposable (46%) and reusable devices (45%). Demographic and clinical characteristics, including macrovascular disease and cardiovascular risk profiles, were broadly similar between the basal insulin subgroup and the overall group of participants (basal insulin subgroup vs total population: males, 48 vs 51%; age, 62 ± 11 vs 61 ± 10 years; T2DM duration, 10 ± 7 vs 11 ± 8 years; HbA<sub>1c</sub>, 9.2 ± 1.8 vs 9.5 ± 2.0%; prior use of oral glucose lowering drugs [OGLDs], 97 vs 93%). Use of OGLDs with insulin tended to be higher in the basal insulin subgroup than in the total population (any OGLD, 89 vs. 70%; biguanides, 64 vs. 50%, sulfonylureas, 63 vs. 43%). **CONCLUSIONS:** The one notable difference between the groups was that those beginning basal insulin alone were more heavily treated with OGLDs beforehand than in the overall population, most commonly biguanides and sulfonylureas. This suggests that they required no lesser intensity of glycaemic management than people starting on other types of insulin.

PDB80

#### MEASURING GLYCOSYLATED HAEMOGLOBIN LEVELS IN PATIENTS WITH DIABETES: IMPACT OF LOWER QOF TARGETS ON ACHIEVEMENT OF CLINICAL INDICATORS AND QOF POINTS

Kingslake SL

AstraZeneca UK Ltd, Luton, UK

**OBJECTIVES:** The 2008/09 Quality and Outcomes Framework (QOF) indicators for measuring glycosylated haemoglobin (HbA<sub>1c</sub>) levels are DM20 and DM07, which measure percentage of diabetic patients with HbA<sub>1c</sub> of either 7.5 or less or 10 or less respectively. New QOF clinical indicators have been agreed for 2009/10: DM23